Global Overview of Pharma Ethical Marketing Code

written by Sanjay Kumar | November 6, 2020

Pharma Ethical Marketing Code: Why is it Imperative and What it Holds for the Pharma Sector?

For quite some time, the government of India has been upholding that it was drafting a mandatory code on pharmaceutical marketing ethics with penal provisions since the UCPMP i.e. voluntary code had not worked. However, it admitted that it has no intention of making the UCPMP mandatory in 2019. Because of the voluntary nature of UCPMP, there is no provision for the Department of Pharmaceuticals (DoP) to directly deal with complaints about unethical practices. Further, as per the voluntary code, any complaint received against a pharma company was to be handled by an ethical committee for pharma marketing practices. Such committees were supposed to be constituted in each pharmaceutical association. The DoP was following up with the associations to implement the code effectively.

What is UCPMP?

UCPMP is a voluntary code issued by the Department of Pharmaceuticals under the Union Ministry of Chemical and Fertilizers relating to marketing practices for pharmaceutical companies as well as the medical devices industry. It was made voluntary for six months from 1st January 2015 and was supposed to be reviewed after six months.

At present, the UCPMP code applies to pharmaceutical companies, medical representatives, agents of pharmaceutical companies such as distributors, wholesalers, retailers, and pharmaceutical manufacturer’s associations.

Key Provisions - Pharmaceutical Marketing Ethics

- No gifts, pecuniary advantages or benefits shall be supplied, offered or promised by a pharma company or its agents to persons qualified to prescribe or supply drugs.
- Companies or their associations/representatives shall not extend any travel facility inside or outside the country; any hospitality like hotel accommodation to healthcare practitioners and their family members under any pretext.
- It also prescribes additional conditions that are to be observed while providing samples.
- Companies or their associations/representatives shall not pay any cash or monetary grants to any healthcare professional under any pretext.
- Further, as per the UCPMP Code, in order to appoint Medical

Practitioners/HCPs as affiliates there should be a written contract, legitimate need for the services must be documented, and criteria for selecting affiliates must be directly related to the identified need. However, the number of affiliates retained must not be greater than the number necessary to achieve the identified need and that the compensation must be reasonable.

Issues

- The companies spend a huge amount on travel, accommodation and other expenditures on the doctors for lavish arrangements of the conferences.
- Support for Advocacy and Training to Health Initiatives (SATHI), had in August alleged that pharmaceutical companies bribe doctors with various gifts.

The government in 2016 had indicated that it would make the code statutory. But now this U-turn raises suspicion of lack of will on the part of the government to keep its commitment and smells of some unfair deals between the government and the pharma companies.[1]

India has not made pharmaceutical marketing ethics a law when other jurisdictions have very elaborated laws and guidelines. This is particularly important for Indian Pharma companies as they market and distribute their products in global jurisdiction. This calls for a look at global positions in terms of pharma marketing.

Global Position Of Pharmaceutical Marketing Ethics Code

USA: Federal Anti-Kickback Law and Regulatory Safe Harbors[2]. The Anti-Kickback Statute ("AKS") 42 U.S.C. § 1320a-7b (SSA § 1128B).

The Federal Anti-Kickback Statute prohibits individuals or entities from *"knowingly or willfully, offering, paying, soliciting or receiving, "Remuneration", directly or indirectly, with the intent to induce or reward business reimbursed under federal healthcare programs*."

Sanctions can include criminal penalties, civil monetary penalties, and exclusion from federal healthcare programs. This applies only to products that are reimbursed under federal health care programs.

It is a criminal felony to offer or pay (or receive) anything of value to a person (e.g., MCO, physician) if one purpose of the offer is to induce the person to use/purchase/recommend a product or service covered under any Federal or state health care program (including Medicare, Medicaid, etc.).

Criminal Penalties 42 U.S.C. § 1320a-7b (SSA § 1128B) up to $25,000 or imprisonment for up to five years, or both can be imposed. Civil monetary penalty is upto $50,000.

With respect to violations of the Anti-Kickback Statute, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

FCA prohibits presenting, or causing to present, a false or fraudulent claim for payment to the U.S., and making or using a false record to get a false claim paid by the government.

Penalties:

Treble damages- $5,500 – $11,000 for each false claim.

In addition to certain exceptions in the AKS itself, there are 25 regulatory safe harbors, three of which are particularly relevant to pharmaceutical manufacturers.

These regulations are not the model of clarity, and often we need to refer to the lengthy preambles to evaluate the scope of particular safe harbors.

Safe harbors: Federally Qualified Health Centers Arrangements, Certain Electronic Prescribing and Electronic Health Records Arrangements, Investments (large publicly owned health care companies; small health care joint ventures; Personal Services Contracts; Discounts and Employee Compensation.

In addition, many states have their own anti-kickback statutes, some of which apply to both private and state healthcare programs (“all payer laws”).

Direct and indirect payments or other transfers of value provided to a U.S. physician or teaching hospital (deemed “covered recipients”).

Payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient.

Ownership and investment interests in the applicable manufacturer that were held by a physician or an immediate family member of a physician.

Annual Reporting: Requires companies to disclose, by July 1 of each year, the value, nature, purpose, and particular recipient of any payment or other economic benefit with a value of at least $50, which the company provides to any covered recipient.

Gift Ban: Manufacturers of prescribed products are prohibited from offering or giving gifts to health care providers. Certain expenditures and gifts are expressly allowed under the Vermont law if specific conditions are met.

European Union: The European Federation of Pharmaceutical Industries and Associations (“EFPIA”) and its Disclosure Code[3] establishes disclosure obligations on EFPIA member companies and companies that are members of an EFPIA member organization.

Many countries have developed codes that include the EFPIA disclosure provisions, including Germany, Greece, Spain, Sweden, Turkey, and the United Kingdom. Several countries have not yet incorporated the disclosure provisions into their codes.

Manufacturers must disclose information, including:

- Transfers of value to HCPs/HCOs related to non-clinical studies, clinical trials, and non-interventional prospective studies that involve the collection of patient data
- Transfers of value to HCOs/third parties to manage an event or to cover registration fees or travel and accommodations
- Consulting fees and related expenses
- Contributions to individual HCPs to cover registration fees, travel and accommodations

France: Requires companies producing or marketing products including, but not limited to, drugs and medical devices (or providing services associated with these products) to make public all agreements with and all benefits in cash or in kind that they provide directly or indirectly to:

- Healthcare professionals and associations of health professionals,
- Medical students and associations representing them, patient associations,
- Hospitals and healthcare institutions,
- Medical societies and foundations,
- Health media companies,
- Prescription and dispensing software companies, and
- Legal entities providing “initial training” to healthcare professionals

Disclosures must be made to the French Ministry of Social Affairs and Health.

Japan: Japan Pharmaceutical Manufacturers Association (“JPMA”) Transparency

Guidelines for the relationship between Corporate Activities and Medical Institutions (2011).[4]

Each member company is required to prepare an in-house “Policy for Transparency” that refers to JPMA guidelines. JPMA gives companies discretion with respect to specific reporting requirements but shall include disclosure obligations regarding at least:

Research and development expenses, Academic research support expenses, Manuscript and writing fees, Information dissemination expenses, etc.

Australia: Medicines Australia Transparency Model[5] was released by Medicines Australia Transparency Working Group on June 21, 2013.

Manufacturers must annually report to Medicines Australia:

- Direct and indirect payments or other transfers of value provided to an Australian healthcare professional during the preceding calendar year
- Direct and indirect payments or other transfers of value provided to a third party at the request of or on behalf of a healthcare professional during the preceding calendar year

Road Ahead

The UCPMP should be converted into Law, as the code for pharmaceutical marketing ethics has not proved to be effective enough. Drugs and Magical Remedies Act, 1954 controls the advertisement of drugs, while the Drugs and Cosmetic Act, 1940 & the Drugs and Cosmetic Rules 1945 regulates import, manufacture, distribution and sale of drugs in India. India does not have a specific law that regulates sales promotion of the drugs by the pharma companies.

The DoP should immediately implement a mandatory mechanism for company disclosure of payments towards doctors and professional bodies, including through third parties.

These disclosures should be made at intervals and put in the public domain. It should include the amount spent, individual or entity to which payment was made and the reason for payment including any services rendered.

[1]https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/

[2]http://www.jpma.or.jp/english/policies_guidelines/transparency_guideline.html

[3] https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/

[4] Pharmaceutical Marketing Ethics

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